

one of the following phrases to the certification:

(1) "if HCFA issues a favorable advisory opinion."

(2) "if HCFA and the OIG issue favorable advisory opinions."

[63 FR 1656, Jan. 9, 1998]

§411.375 Fees for the cost of advisory opinions.

(a) *Initial payment.* Parties must include with each request for an advisory opinion submitted through December 31, 1998, a check or money order payable to HCFA for \$250. For requests submitted after this date, parties must include a check or money order in this amount, unless HCFA has revised the amount of the initial fee in a program issuance, in which case, the requestor must include the revised amount. This initial payment is nonrefundable.

(b) *How costs are calculated.* Before issuing the advisory opinion, HCFA calculates the costs the Department has incurred in responding to the request. The calculation includes the costs of salaries, benefits, and overhead for analysts, attorneys, and others who have worked on the request, as well as administrative and supervisory support for these individuals.

(c) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If HCFA estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, HCFA notifies the requestor.

(3) If HCFA notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, HCFA stops processing the request until the requestor makes a written request for HCFA to continue. If HCFA is delayed in processing the request for an advisory opinion because of this procedure, the time within which HCFA must issue an advisory opinion is suspended until the re-

questor asks HCFA to continue working on the request.

(4) If the requestor chooses not to pay for HCFA to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs HCFA has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs HCFA has incurred in responding to the request are greater than the amount the requestor has paid, HCFA, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. HCFA does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid HCFA the total amount due for the costs of processing the request, HCFA issues the advisory opinion. The time period HCFA has for issuing advisory opinions is suspended from the time HCFA notifies the requestor of the amount owed until the time HCFA receives full payment.

(d) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in §411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that HCFA notifies the requestor that it needs an outside expert opinion until the time HCFA receives that opinion.

[63 FR 1656, Jan. 9, 1998]

§411.377 Expert opinions from outside sources.

(a) HCFA may request expert advice from qualified sources if HCFA believes that the advice is necessary to respond to a request for an advisory opinion. For example, HCFA may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If HCFA determines that it needs to obtain expert advice in order to issue a requested advisory opinion, HCFA notifies the requestor of that

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fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in §411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once HCFA has received payment for the estimated cost of the expert advice, HCFA arranges for the expert to provide a prompt review of the issue or issues in question. HCFA considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs HCFA has incurred in responding to the request, and the responsibility of the requestor, as described in §411.375(c).

[63 FR 1657, Jan. 9, 1998]

§411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before HCFA issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in §411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in §411.375. HCFA reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

[63 FR 1657, Jan. 9, 1998]

§411.379 When HCFA accepts a request.

(a) Upon receiving a request for an advisory opinion, HCFA promptly makes an initial determination of whether the request includes all of the information it will need to process the request.

(b) Within 15 working days of receiving the request, HCFA—

(1) Formally accepts the request for an advisory opinion;

(2) Notifies the requestor about the additional information it needs, or

(3) Declines to formally accept the request.

(c) If the requestor provides the additional information HCFA has requested, or otherwise resubmits the request, HCFA processes the resubmis-

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sion in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

(d) Upon accepting the request, HCFA notifies the requestor by regular U.S. mail of the date that HCFA formally accepted the request.

(e) The 90-day period that HCFA has to issue an advisory opinion set forth in §411.380(c) does not begin until HCFA has formally accepted the request for an advisory opinion.

[63 FR 1657, Jan. 9, 1998]

§411.380 When HCFA issues a formal advisory opinion.

(a) HCFA considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized HCFA official.

(b) An advisory opinion contains a description of the material facts known to HCFA that relate to the arrangement that is the subject of the advisory opinion, and states HCFA's opinion about the subject matter of the request based on those facts. If necessary, HCFA includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) HCFA issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that HCFA determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period.

(2) If the 90th day falls on a Saturday, Sunday, or Federal holiday, the time period ends at the close of the first business day following the weekend or holiday;

(3) The 90-day period is suspended from the time HCFA—

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in §411.375(c)(2) until HCFA receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until HCFA receives the additional information;